

Remarks

Claims 9 and 21 have been amended, no claims are canceled or added; as a result, claims 9-18 and 20-21 are now pending in this application.

Claims 9 and 21 have been amended to recite “animal plasma from which the fibrin and albumin have been separated.” This amendment is supported, for example, at page 14, line 21 of the specification.

Clarification of the Declaration under 37 C.F.R. § 1.132 submitted by Joy. M. Campbell on September 26, 2006

The Examiner is requested to note that in view of the amendments to claims 9 and 21, Applicants are no longer relying on the Declaration under 37 C.F.R. § 1.132 submitted by Joy. M. Campbell on September 26, 2006. —

35 U.S.C. §112 Rejection of the Claims

Claims 9-18 and 20-21 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that the “specification and the claims as originally filed do not provide a clear support for the phrase ‘from which the fibrin has been separated’ and the applicant has not pointed out where the support comes from” (e.g., page 5, Final Office Action mailed January 4, 2007). Applicants respectfully traverse the rejection.

In the Amendment and Response submitted September 26, 2006 (which is incorporated herein by reference), Applicants submitted that the “amendments to claims 9 and 21 . . . are supported by the specification at page 10, full paragraph 3 and at page 13, last paragraph” (e.g., page 5). Further, the specification recites the preferred manufacturing method for globulin concentrate that includes “[e]ntrifuge to remove fibrin” (e.g., Example 4, page 25).

In summary, the proper standard for a “written description” rejection is whether or not the specification indicates to one of ordinary skill in the art that the Applicants had possession of the invention as claimed. At a minimum, the portions of the application discussed above and the

express statement “[c]entrifuge to remove fibrin” indicate that one of ordinary skill in the art would recognize that Applicants did, in fact, possess the claimed invention at the time of filing.

Therefore, Applicants respectfully submit that claims 9-18 and 20-21 do satisfy the requirements of §112, first paragraph. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

35 U.S.C. §103(a) Rejection of the Claims

Claims 9-18 and 20-21 were rejected under 35 U.S.C. § 103(a) as obvious over Newson et al. (U.S. Patent No. 4,096,244), in view of Yoder (U.S. Pat. No. 5,372,811) and Austin et al. (U.S. Pat. No. 5,143,257), and evidence disclosed in p. 10 of the specification, for reasons set forth in the Office Action mailed June 29, 2006. Claims 9 and 21 have been amended. However, to the extent that the rejection applies to claims 9-18 and 20-21, Applicants respectfully traverse the rejection.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” M.P.E.P. § 2143.

Applicants respectfully submit that the cited documents do not disclose or suggest all of the language recited in the present claims. For example, Newson et al. disclose a dried particulate porcine or bovine blood serum containing active immunoglobulins and having a sodium chloride content of less than about 3% by weight (see, e.g., claim 1). Newson et al. also disclose that a “further advantage of the present invention is that the resultant dried serum contains appreciable quantities of other proteins, especially **albumin**, which are nutritious to the piglets” (e.g., column 4, lines 50-53, emphasis added). Further, Newson et al. disclose Examples 1 and 2, which contain 45% and 59.7% **albumin**, respectively.

Yoder discloses a feed supplement that includes animal plasma protein and a microbial fermentation product of primarily amylase which are blended and spray dried. Yoder further discloses that the animal plasma protein contains “about 60% **albumin** and about 40% globulin” (e.g., column 3, lines 29-31, emphasis added).

Austin et al. disclose a system for proportional liquid dispensing of two liquids and are silent regarding plasma, fibrin, and albumin. In contrast to the claimed invention, Applicants respectfully submit that the cited documents do not disclose a “supplement comprising a water miscible and stable immunoglobulin concentrate the source of which is animal plasma from which the fibrin and **albumin** have been separated” (e.g., independent claims 9 and 21, emphasis added).

Applicants further submit that there is no suggestion or motivation, either in the documents or in the knowledge generally available to one of ordinary skill in the art, to modify the documents. Rather, as discussed above, Newson et al. actually teach away from the present invention by preferring their dried serum to contain albumin because albumin is nutritious to piglets. “If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).”

M.P.E.P. § 2143.01. As a result, Applicants respectfully submit that one of ordinary skill would not be motivated to go directly against the teachings of Newson et al.

Applicants further submit that Yoder, Austin et al., and evidence disclosed in p. 10 of the specification do not disclose the suggestion or motivation that would correct the deficiencies of Newson et al. noted herein above.

The Examiner alleged that the “declarations by Campbell and Weaver are not commensurate with the scope of the claimed invention . . . The compositions of the declarations are plasma proteins and are not limited to immunoglobins” (e.g., page 3, Final Office Action mailed January 4, 2007). Applicants respectfully disagree.

The Examiner is requested to consider the Supplemental Declaration under 37 C.F.R. § 1.132 submitted by Dr. Eric M. Weaver on March 28, 2007. In this Supplemental Declaration under 37 C.F.R. § 1.132, Dr. Weaver declared that the “concentrated spray dried plasma product” and the “plasma product supplementation,” as described in # 13 and #16, respectively, of the Declaration under 37 C.F.R. § 1.132 submitted by Eric M. Weaver on September 26, 2006 were spray-dried animal plasma from which the fibrin has been separated.

Applicants respectfully submit that the Examiner’s conclusion of obviousness must be reviewed in view of the unexpected results achieved by administering immunoglobulin

concentrate (plasma with fibrin and albumin removed). For example, the Declaration under 37 C.F.R. § 1.132 submitted by Eric M. Weaver on September 26, 2006, describes the results of administering immunoglobulin concentrate in both water and feed of pigs when the concentration in the feed is pre-optimized. Table 1 in # 13 describes a trial where pigs were offered a diet containing 5% spray dried plasma protein and a water solution containing various concentrations of globulin concentrate (plasma with fibrin and albumin removed). The globulin concentrate was prepared as described in the specification. The globulin concentrate had 40-50% IgG. The data summarized on Table 1 in # 13 lead Dr. Weaver to conclude that an unexpected increase (198%) in average daily gain occurred when young pigs receiving feed supplemented with immunoglobulin concentrate also received immunoglobulin concentrate via their water supply. See paragraph 15. These results are unexpected and permit ADG and ADFI to be unexpectedly increased to an extent that cannot be achieved by simply increasing the amount of immunoglobulin concentrate in the feed.

Claims 10-18 and 20 depends from claim 9. Therefore, claims 10-18 and 20 are patentable for at least the reasons discussed herein above for the patentability of claim 9.

As such, Applicants respectfully submit that pending claims 9-18 and 20-21 are not obvious over the combination of Newson et al. in view of Yoder, Austin et al., and evidence disclosed in p. 10 of the specification. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 10/613,633

Filing Date: July 3, 2003

Title: WATER-SOLUBLE GLOBULIN CONCENTRATE FOR IMPROVING GROWTH IN ANIMALS

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CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 4 day of April 2007.

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